REMARKS

Currently, claims 69, 70, 72, and 74 are pending and under examination in this application.

I. *Rejection Under 35 U.S.C. § 112, first paragraph*

The claims stand rejected under 35 U.S.C. § 112, first paragraph, as assertedly lacking written description support in the specification. (Final Office Action at pages 2-5.) Specifically, the Office asserts that the specification does not show that Applicants were in possession of "the plethora of modifications of a nucleic acid polymerase, especially, archaeal nucleic acid polymerases, as encompassed by the claims" because the modifications encompass "*any* nucleic acid change, variation, mutation or functional modification, none of which have been described." Applicants respectfully submit that the Office has misapplied the requirements for an adequate written description in setting forth this rejection.

U.S. law sets forth the requirements for an adequate written description to support a claimed invention. The Office does not cite any controlling statute or case law to support its position, but instead broadly asserts that the present application fails to disclose "a representative number of the modified species", and thus lacks an adequate written description of the claimed invention. Applicants respectfully submit that the Office has failed to apply the law appropriately.

Under U.S. law, a claimed invention satisfies the written description requirement of 35 U.S.C. § 112, first paragraph, if an adequate amount of information is provided by the application, taken into consideration with the state of the art, to indicate that the applicant was in possession (either physically or constructively) of the claimed invention. For example, the Federal Circuit has said:

> Precedent illustrates that the determination of what is needed to support generic claims to biological subject matter depends on a variety of factors, such as the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, the predictability of the aspect at issue, and other considerations appropriate to the subject matter.

(*Capon v. Dudas*, 418 F.3d 1349, 1359, 76 USPQ2d 1078, 1085 (Fed. Cir. 2005) reversing USPTO Board's ruling that claims lacked an adequate written description on the grounds that the specification did not describe the structure of a claimed DNA material. The Board erred in applying a *per se* rule that a description of the structure of claimed DNA material was required in all cases.)

Furthermore, in that case, the Federal Circuit explained:

> The descriptive text needed to meet these requirements varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence. The law must be applied to each invention that enters the patent process, for each patented advance is novel in relation to the state of the science. Since the law is applied to each invention in view of the state of relevant knowledge, its application will vary with differences in the state of knowledge in the field and differences in the predictability of the science.

> The 'written description' requirement must be applied in the context of the particular invention and the state of the knowledge. The Board's rule that the nucleotide sequences of the chimeric genes must be fully presented, although the nucleotide sequences of the component DNA are known, is an inappropriate generalization. When the prior art includes the nucleotide information, precedent does not set a *per se* rule that the information must be determined afresh.

Id. at 418 F.3d 1357-58, 76 USPQ2d 1084-85.

In addition, U.S. law states that the written description requirement of 35 U.S.C. § 112, first paragraph can be satisfied in the absence of a specific disclosure of species encompassed by a generic term, where those species are known in the art.

> [A] requirement that patentees recite known DNA structures, if one existed, would serve no goal of the written description requirement. It would neither enforce the quid pro quo between the patentee and the public by forcing the disclosure of new information, nor would it be necessary to demonstrate to a person of ordinary skill in the art that the patentee was in possession of the claimed invention. As we stated in *Capon*, "[t]he 'written description' requirement states that the patentee must describe the invention; it does not state that every invention must be described in the same way. As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution." Indeed, the forced recitation of known sequences in patent disclosures would only add unnecessary bulk to the specification. Accordingly we hold that where, as in this case, accessible literature sources clearly provided, as of the relevant date, genes and their nucleotide sequences (here 'essential genes'), satisfaction of the written description requirement does not require either the recitation or incorporation by reference (where permitted) of such genes and sequences.

(*Falkner v. Inglis*, 448 F.3d 1357, 1366-67, 79 USPQ2d 1001, 1007-08 (Fed. Cir. 2006) affirming USPTO Board's holding of adequate written description in priority document of using poxvirus as a vaccine even though the earlier-filed application only provided specific examples using a herpesvirus. The court reasoned that, because the specification provided three textual passages that stated that poxvirus could be used, and the state of the art was such that one of skill in the art, with the textual description and his or her knowledge of the genome, could make the invention, the fact that the specification did not include a working example that used a poxvirus, or show that the inventors had actually reduced to practice an embodiment of the invention using a poxvirus, did not support a finding of a lack of written description.)

As in the case of *Falkner v. Inglis*, the present specification provides a textual passage that states that the invention can be practiced with PEF and "polymerase mutants, truncated versions of polymerases, mixtures of polymerases, and polymerase-additive combinations" (specification at page 61, lines 26-27). Furthermore, as in the cases of *Falkner v. Inglis* and *Capon v. Dudas*, at the time of filing of the present application, mutant, truncated, etc. Archaeal polymerases were known in the art. Their respective sequences thus need not be disclosed specifically in the specification for there to be adequate written description of those mutants, etc.

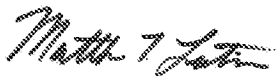
Because the present specification adheres to U.S. legal standards for an adequate written description of "modified archaeal nucleic acid polymerases", Applicants submit that the rejection of claims 69, 70, 72, and 74 is improper and should be withdrawn.

II. *Conclusion*

In view of the foregoing remarks, Applicants submit that this application is in condition for allowance. If the Office believes anything further is necessary to place this application in even better condition for allowance, Applicants request that their undersigned representative be contacted at the telephone number listed below to discuss the remaining issues.

Please grant any extensions of time required to enter this Response and charge any required fees to Deposit Account No. 50-3740.

Respectfully submitted,
Holly HOGREFE et al.



Date: 26 September 2007

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